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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appln. No.	:	10/677,962	Confirmation No. 9258
Applicant	:	Mark Carter	
Filed	:	10/01/03	
Art Unit	:	1791	
Examiner	:	Michael T. Piery	
Title	:	CATHETER SHAFT HAVING VARIABLE THICKNESS LAYERS AND METHOD OF MAKING	
Docket No.:	:	ACSC-65631 (G1935USD1)	
Customer No.	:	24201	August 7, 2009

Mail Stop Appeal Brief - PATENTS
Commissioner for Patents

RESPONSE TO NON-COMPLIANT APPEAL BRIEF

Dear Sir:

This is in response to non-compliant appeal brief dated July 16, 2009.

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed on March 12, 2009. A request for a one month extension of time along with the requisite fees is attached hereto.

INTRODUCTION

The present invention relates to catheters and more particularly pertains to a method of making a catheter having two layers with a co-tapered structure wherein a first layer tapers to a smaller thickness at its distal end while a second layer tapers to a smaller thickness at its proximal end. Previously employed methods for manufacturing such a structure have been unable to provide an adequately short and tailored transition. The present application, U.S. Serial No. 10/677,962 was filed October 1, 2003 and is a divisional of U.S. Serial No. 09/707,681 that was filed November 6, 2000.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC. (formerly Advanced Cardiovascular Systems, Inc., the assignee of record), 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Par, Illinois 60664-3500. This application was originally assigned by the inventor, MARK CARTER to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed October 11, 2001 and October 21, 2001 respectively, which was recorded by the US Patent Office on October 25, 2001 beginning at Reel 012421, Frame 0441.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

The application was originally filed with claims 1-30. Claims 1-24 were canceled by Preliminary Amendment to leave 6 method claims (25-30) pending. Claim 31 was added during the course of prosecutions. Claims 25-31 are currently pending, are under final rejection and are being appealed. A clean copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to the final Office Action of November 13, 2008.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The rejected claims are all directed to a method of manufacturing a "co-tapered" catheter shaft. More particularly, the method provides for the co-extrusion of two different materials by two gear pumps wherein the desired co-tapered configuration is achieved with the simultaneous reversing of one gear pump and the increasing the speed of the second gear pump. Two independent claims are under appeal.

Independent claim 25 is supported in the specification and drawings as follows:

25. A method of making an elongated catheter shaft having at least a first (page 3, line 11; Fig. 2, #26) and second layer (page 3, line 12, Fig. 2, #27), and a co-tapered section (page 3, line 13, Fig. 2, #30) in which the first layer tapers to a smaller wall thickness and the second layer tapers inversely to the taper of the first layer (page 3, lines 10-13) comprising:

a) extruding the first layer from an extruder having a first gear pump (page 19, lines 15-16; Fig. 8, #64) at an output end thereof and co-extruding the second layer with the first layer from a second extruder having a second gear pump (page 19, lines 13-16; Fig. 8, #64) at an output end thereof; and

b) forming the co-tapered section of the shaft by reversing the rotation of the first gear pump (page 20, lines 13-20; Fig. 10) to at least in part form the taper in the first layer and increasing the speed of the second gear pump (page 20, lines 3-6; Fig. 10) from a first speed to a second speed to form the inverse taper in the second layer.

Independent claim 30 is supported in the drawings and specification as follows:

30. A method of making an elongated catheter (page 3, line 6; Fig. 1, #11) shaft having at least a first (page 3, line 11; Fig. 2, #26) and second layer (page 3, line 12; Fig. 2, #27), and a section which is located between ends of the shaft and in which the first layer tapers distally to a smaller wall thickness (page 3, lines 10-13), comprising extruding the first layer from an extruder having a first gear pump (page 19, lines 13-16; Fig. 8, #64) at an output end thereof and co-extruding the second layer with the first layer from a second extruder (page 19, lines 13-16; Fig. 8, #62), and forming the section of the shaft by reversing the rotation of the first gear pump to at least in part form the taper in the first layer (page 20, lines 13-20).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the Final Office Action dated August 13, 2008, the independent claims were rejected as follows:

GROUND I

Claims 25-27, 29 and 30 were rejected under 35 U.S.C. § 103(a) as obvious over Harris (USPN 5,725,814) in view of Johnson (USPN 3,611,504).

GROUND II

Claim 28 was rejected under 35 U.S.C. § 103(a) obvious over Harris (USPN 5,725,814) in view of Johnson (USPN 3,611,504) and further in view of Tiernan et al (USPN 6,579,484).

GROUND III

Claim 31 was rejected under 35 U.S.C. § 103(a) obvious over Harris (USPN 5,725,814) in view of Johnson (USPN 3,611,504) and further in view of Strum et al (USPN 4,824,618).

VII. ARGUMENT

Pursuant to the Final Office Action dated August 13, 2008, the independent claims were rejected as follows:

Each and every claim calls for the method to include a step in which one of two gear pumps is reversed **during** the extrusion process. None of the cited references suggest such a step during the coextrusion of two materials.

GROUND I

Claims 25-27, 29 and 30 were rejected under 35 U.S.C. § 103(a) as obvious over Harris (USPN 5,725,814) in view of Johnson (USPN 3,611,504).

The Examiner relies on the Harris reference (Exhibit 2) as teaching the coextrusion of two materials with two gear pumps to form a co-taper by decreasing the rotation of a first gear pump and increasing the speed of the second gear pump. As such, this teaching comprises precisely the prior art that the present invention improves upon as was specifically set forth in the specification at page 2, line 20. The Examiner then relies on the Johnson reference (Exhibit 3) as teaching the reversal of an "extruder" in order to prevent "drool" of the plastic melt and asserts that it would be obvious to combine a method of using two gear pumps to manufacture a catheter shaft having co-tapered layers with a method of preventing "drool" to arrive at the present invention as claimed. This combination however misses the point. The secondary reference is directed to an injection molding process that exclusively employs a feed screw 14, **not a gear pump**. Moreover, the primary reference teaches that the use of gear pumps comprises an improvement over the use of feed screws as feed screws were prone to "drool" and were therefore incapable of relatively quickly changing from the output of one extruder to another or to vary the content so that the extrudate changes gradually in a precisely controlled fashion (col 1, lines 46-59). Although the reference acknowledges that there are, in fact, slight leakages within gear pumps that cause some dependence on output back pressure (col 4, lines 6-8), the reference goes on to teach that "when a gear pump stops, it has the effect equivalent to closing off the output pipe from the extruder (col 4, lines 16-18). Additionally, the reference teaches at col 4, line 3-5 that "the output of a gear pump is proportional to RPM essentially regardless of what happens to the pressure at the output." As such, rather than forming a "co-taper," the reference teaches that stopping one gear pump during the coextrusion of two materials would in fact cause the output of one material to stop completely thereby resulting in an abrupt transition from one material to the other. Moreover, in view of the teaching with regard to the proportionality of RPM to output, one would expect a reversal of one gear pump, i.e. a negative RPM, to result in the removal of material rather than a tapered output. Notwithstanding the teaching of the secondary reference that reversal of a **feed screw** prevents drool, it is respectfully submitted that the reversing one of two gear pumps during the extrusion process unexpectedly results in the desired short and tailored co-taper of a catheter shaft.

GROUND II

Claim 28 was rejected under 35 U.S.C. § 103(a) obvious over Harris (USPN 5,725,814) in view of Johnson (USPN 3,611,504) and further in view of Tiernan et al (USPN 6,579,484).

The Tiernan reference was cited in the rejection of dependent claim 28 for its disclosure of the length of the taper and as such does not overcome the shortcomings of the Harris and Johnson references with regard to rendering obvious the **method** that is claimed in underlying independent claim 25 as was argued above. As consequence, all claims depending from claim 25 similarly avoid obviousness.

GROUND III

Claim 31 was rejected under 35 U.S.C. § 103(a) obvious over Harris (USPN 5,725,814) in view of Johnson (USPN 3,611,504) and further in view of Strum et al (USPN 4,824,618).

The Strum reference was cited in the rejection of dependent claim 31 for its disclosure of a particular extruder configuration and as such does not overcome the shortcomings of the Harris and Johnson references with regard to rendering obvious the **method** that is claimed in the underlying independent claim 25 as was argued above. As consequence, all claims depending from claim 25 similarly avoid obviousness.

VIII. CLAIMS APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

XI. CONCLUSION

For the foregoing reasons, it is submitted that the present invention as claimed is not obvious over any combination of the cited references and that the Examiner’s rejections of claims 25-31 were therefore erroneous. Reversal of the rejections of claims 25-31 is therefore respectfully requested.

Respectfully submitted,

FULWIDER PATTON LLP

/Gunther O. Hanke/
Gunther O. Hanke, Reg. No. 32,989

GOH:lm

LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
1	Appealed Claims
2	U.S. Patent No. 5,725,814 - Harris
3	U.S. Patent No. 3,611,504 - Johnson

EXHIBIT 1

EXHIBIT 1

CLAIMS

1-24. Canceled.

25. A method of making an elongated catheter shaft having at least a first and second layer, and a co-tapered section in which the first layer tapers to a smaller wall thickness and the second layer tapers inversely to the taper of the first layer comprising

> a) extruding the first layer from an extruder having a first gear pump at an output end thereof and co-extruding the second layer with the first layer from a second extruder having a second gear pump at an output end thereof; and
>
> b) forming the co-tapered section of the shaft by reversing the rotation of the first gear pump to at least in part form the taper in the first layer and increasing the speed of the second gear pump from a first speed to a second speed to form the inverse taper in the second layer.

26. The method of claim 25 including, after (b), forming a non co-tapered distal section of the shaft adjacent to the co-tapered section by decreasing the speed of the second gear pump from the second speed to a third speed greater than the first speed of the second gear pump and less than the second speed of the second gear pump.

27. The method of claim 25 wherein the shaft has a proximal section and distal section on either end of the co-tapered section having different relative proportions of the first and second layers therein, and including forming the distal section by changing the rotation of the first gear pump from the reversed rotation to a forward rotation and setting the speed of the first gear pump at a second speed less than a first speed of the first gear pump used to form the proximal section.

28. The method of claim 27 wherein the co-tapered section has a length of about 13 cm to about 25 cm, and forming the distal section of the shaft includes decreasing the speed of the second gear pump from the second speed to a third speed.

29. The method of claim 27 wherein forming the co-tapered section of the shaft includes decreasing a speed of the first gear pump from the first speed to a third speed.

30. A method of making an elongated catheter shaft having at least a first and second layer, and a section which is located between ends of the shaft and in which the first layer tapers distally to a smaller wall thickness, comprising extruding the first layer from an extruder having a first gear pump at an output end thereof and co-extruding the second layer with the first layer from a second extruder, and forming the section of the shaft by reversing the rotation of the first gear pump to at least in part form the taper in the first layer.

31. The method of claim 25 wherein the extruder is part of an extrusion apparatus having tip with a tapered section between a uniform diameter section and a die-end section, a die with the die-end section of the tip therein from a polymer-receiving end of the die to an opposite output end of the die to form the catheter shaft as a tubular extrudate, and an extended flow divider at a location which receives a first layer polymeric material and a second layer polymeric material from the gear pumps, and which separates the flow of the first layer polymeric material from the second layer polymeric material upstream of the die, and which extends to an end of the tapered section of the tip at a junction between the tapered section and the die-end section of the tip, and the method includes separating the first and second layer polymeric materials with the extended flow divider until the polymeric materials are at the polymer-receiving end of the die.